510(k) Summary of Safety and Effectiveness

K081806

Submitted by: William Hung, DDS.,JD.
CEO

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NOV - 7 2008

Date of Submission: June 9, 2008

Classification Name: Endosseous dental implant 21 CFR 872.3640 and endosseous dental implant abutment 21 CFR 872.3630

Trade Name: IDI Implant Systems

Legally Marketed Device: NobelReplace Hexagonal Implant K073142

Device Description:
IDI Implant Systems are threaded root-form dental implants intended for use in the upper and lower jaw arches to support prosthetic devices, such as an artificial tooth, in order to restore esthetics and chewing function to partially or fully edentulous patients. Also included are straight abutments which provide cemented and screw retained restorative options.

Indications for Use:
IDI Implant Systems (IDI Fixtures and IDI Abutments with screws) are endosseous implants intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as an artifical tooth, in order to restore patient esthetics and chewing function. Straight abutments indicated for both screw retained and cemented restorations are included. The implants are indicated for single or multiple unit restorations and can be used in splinted and non-splinted applications. The device is intended for immediate loading when good primary stability has been achieved and with appropriate occlusal loading.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 7 2008

IDI Biomedical LLC
C/o Ms. Angela Blackwell
Senior Consultant
Biologics Consulting Group
104 2nd Street SE
Catawba, North Carolina 28609

Re: K081806
Trade/Device Name: IDI Implant System
Regulation Number: 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE, NHA
Dated: November 4, 2008
Received: November 4, 2008

Dear Ms. Angela Blackwell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu S. Lin, Ph. D FOR DR. CHIU LIN
Division Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use:

510(k) Number (if known): K081806

Device Name: IDI Implant system

Indication For Use:

IDI Implant System are endosseous implants intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as an artificial tooth, in order to restore patient esthetics and chewing function. Straight abutments indicated for both screw retained and cemented restorations are included. The implants are indicated for single or multiple unit restorations and can be used in splinted and non-splinted applications. The device' is intended for immediate loading when good primary stability has been achieved and with appropriate occlusal loading.

Prescription Use x (Part 21 CFR801 Subpart D) AND/OR

Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K081806